

**BANNER
PHARMACAPS**



August 8, 2002

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

CITIZEN PETITION

Dear Sir or Madam:

This Citizen's Petition is submitted by the undersigned on behalf of Banner Pharmacaps, Inc. under the authority of 21 CFR §10.30 and 21 CFR §330.10. The petitioner is requesting an amendment of the proposed OTC monograph for laxatives.

A. Action Requested

By this petition, the Food and Drug Administration is being requested to amend the proposed OTC monograph for laxatives to state that docusate calcium (dioctyl calcium sulfosuccinate) is an interchangeable ingredient with docusate sodium (dioctyl sodium sulfosuccinate) in proposed monograph combinations.

B. Statement of Grounds

67 FR 31125, Status of Certain Additional Over-the-Counter Drug Category II and III Active Ingredients (Final Rule), addresses the removal of casanthranol from the OTC market by November 5, 2002. Within the rule, it is stated that "Approximately 125 products contain casanthranol and docusate sodium, a proposed monograph laxative ingredient. These combination products could be reformulated to eliminate the casanthranol, replace the casanthranol with sennosides A and B or sodium carboxymethylcellulose (proposed monograph combinations with docusate sodium Sec. 334.30(i)(3) and (j) (58 FR 46589 at 46595, September 2, 1993)), or possibly increase the quantity of docusate sodium in the product, in conformance with the proposed monograph."

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In accordance with 43 FR 55466, OTC Combination Drug Products, and Docket No. 78D-0322, General Guidelines for OTC Drug Combination Products, we request that the monograph state and list that docusate sodium and docusate calcium are interchangeable, and that combinations permitted for marketing under the monograph will include docusate calcium.

In support of this petition, the following information is being provided:

- (1) Docusate calcium is a proposed monograph single ingredient. It is in the same pharmacological class as docusate sodium (stool softener, emollient, surfactant) and has the same therapeutic effect. Docusate calcium is marketed in the US under the name "Surfak® LiquiGels®" by Pharmacia and by several generic companies as well. Attachment 1 is product label and information.
- (2) The different salts of docusate (sodium, calcium, or potassium) are considered interchangeable, as described in Martindale: The Extra Pharmacopeia¹. Attachment 2 is the Martindale monograph, page 1088.
- (3) Given the molecular structures of the salts, it can be determined that dosages are equivalent (i.e., 100 mg of docusate sodium is equivalent to 100 mg of docusate calcium). Remington's Pharmaceutical Sciences² substantiates the therapeutic and dosage equivalence of the salts. Attachment 3 is Remington's, page 789.
- (4) "Docusates" are considered interchangeable with regards to their pharmacological and therapeutic effects as supported by their summary in Goodman & Gilman's The Pharmacological Basis of Therapeutics³. Docusate sodium is considered the prototype and is most widely used, but no other distinctions are made in respect to dosage, adverse effects, or usage. Attachment 4 is Goodman & Gilman's, page 924.

C. Environmental Impact

The applicant claims a categorical exclusion under 21 CFR §25.31.


D. Economic Impact

Information will be provided upon request of the Commissioner.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which are unfavorable to the petition.

Respectfully submitted by:



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Phone: (800) 447-1144 ext. 3312

(4) Attachments

References:

1. Martindale: The Extra Pharmacopeia. The Pharmaceutical Press, 29th edition, 1989, pg. 1088.
2. Remington's Pharmaceutical Sciences. Mack Publishing Company, 18th edition, 1990, pg. 789.
3. Goodman & Gilman's The Pharmacological Basis of Therapeutics. McGraw-Hill, 9th edition, 1996, pg. 924.

ATTACHMENT 1